

### REMARKS

Claims 1-12, 15-23, 25 and 85 will be pending in the application upon entry of the present amendment, which cancels claims 13, 14, 24, and 26-84 and adds new claim 85. Claims 1-4, 15, and 22 have been amended. Several of the amendments are made solely in the interest of improving the clarity of the claim language. No new matter has been added.

#### 35 U.S.C. § 112

Claims 3, 12, and 15 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite (Office action at page 2). Although Applicant does not concede that the metes and bounds of those claims were insufficiently clear, the claims have been amended. With respect to claim 3, the "comprising" language has been removed; in claim 12, the amendment introduces the standard Markush language; and in claim 15, a thickness range has been included. Claims 12 and 15 do retain the term "wherein," but Applicant fails to see how that standard term can render the claims indefinite, particularly in view of the present amendments.

Claim 14 was rejected as "an omnibus type claim" (Office action at page 3). As claim 14 has been canceled, this ground for rejection is now moot.

Claims 22-24 were rejected because these claims relate "structure to an unknown" (Office action at page 3). Claim 22 has been amended to remove the reference to "force displacement characteristics that do not restrict tissue movement" and claim 24 has been canceled. Applicant believes claim 23 was rejected because of its dependence on claim 22. As claim 22 has been amended, claim 23 should be considered sufficiently definite for at least the same reasons as amended claim 22.

In view of the present amendments, the Examiner is asked to reconsider and withdraw this ground for rejection. Should the Examiner continue to have concerns regarding clarity, the favor of a telephone call to the undersigned is respectfully requested to discuss mutually acceptable claim language.

35 U.S.C. §102(b)

Claims 1, 8-10, 12, 14-16, 18-21, and 25 were rejected under 35 U.S.C. § 102(b) as being anticipated by Forst *et al.* (U.S. Patent No. 6,071,291; herein "Forst") (Office action at pages 4-5).

In view of the present amendment of claim 1, from which the remaining claims depend, Applicant asks the Examiner to reconsider and withdraw this ground for rejection. Claim 1 has been amended to specify that the implant includes a biocompatible film comprising one or more films of *axially oriented polymer or copolymer*. Forst does not describe a soft tissue implant, much less one having one or more films of axially oriented polymer or copolymer. The Examiner recognizes as much, stating, "Forst et al remains silent as to utilizing polymers such as polypropylene, silicone, etc..." (Office action at page 5). As the test for anticipation is a test of identity, Forst's lattice cannot anticipate the soft-tissue implant now claimed. As noted, claims 8-10, 12, 15, 16, 18-21, and 25 depend or ultimately depend from claim 1 and, thus, incorporate the limitation amended claim 1 by reference. Accordingly, for at least the same reasons set forth with respect to amended claim 1, claims 8-10, 12, 15, 16, 18-21, and 25 cannot be anticipated by Forst.

35 U.S.C. § 102 / 103

Two of Applicant's claims, claims 17 and 22, were rejected in the alternative as being anticipated or obvious over Forst (Office action at page 5).

In view of the present amendment, the Examiner is asked to reconsider and withdraw this ground for rejection. Claims 17 and 22 depend from claim 1, which is now limited as described above. As Forst does not disclose a soft tissue implant having one or more films of axially oriented polymer or copolymer, Forst cannot anticipate either claim 17 or claim 22, which depend from claim 1 and therefore incorporate the limitations of claim 1. Similarly, as there can be no *prima facie* case of obviousness unless the prior art teaches or suggests all the limitations of the claims, Forst cannot render the subject matter now covered by claims 17 and 22 obvious.

Four other claims, claims 2-3 and 23-24, were rejected as being unpatentable over Forst in view of Hardwick *et al.* (U.S. Patent No. 6,328,765; herein, "Hardwick"). The Examiner states (Office action at pages 5-6; emphasis added):

Forst et al discloses a non-woven *soft tissue implant* as discussed above including specifying *biocompatible* tissue. However, Forst et al remains silent as to utilizing polymers such as polypropylene, silicone, etc ... Hardwick et al teaches another non-woven surgical mesh (fig. 1a-1b and 3a-3c) made of polymer such as polypropylene, silicone, etc... *for the purpose of being biocompatible*. It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the biocompatible polymer of Hardwick et al for the biocompatible material in the implant of Forst et al because *such a modification amounts to mere substitution of one functionally equivalent material for another* within the art of surgical meshes.

Applicant respectfully disagrees. First, the lattice described by Forst is not a soft tissue implant; it is "for the fixation of bone parts or for the bridging of bone defects, particularly in the region of the skull and jaw" (1:3-5; *see also* FIG. 2). Second, the Examiner's references to biocompatibility cannot support a *prima facie* case of obviousness. Regardless of their purpose or type, virtually all surgical implants are biocompatible. As one would always select a biocompatible material, there is no motivation to select, from all of the possible biocompatible materials, the non-absorbable polymer recited in claim 2 (or, much less, any of the particular non-absorbable polymers recited in claim 3). As the Examiner knows, there must be some suggestion or motivation to modify a prior art reference or to combine reference teachings. MPEP at 2143, citing *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). The mere fact that non-absorbable polymers existed or were used by Hardwick is not enough. Forst's selection of titanium allowed his lattice to perform the bone fixation function for which it was intended. There is no reason why one of ordinary skill in the art would replace titanium with a non-absorbable polymer, nor could one expect that making such a substitution would produce a successful soft tissue implant. As noted, Forst's lattice is for bone fixation and Hardwick devised a "porous permeable shell" (9:28-29) to be used together with "[a]t least one tissue stimulating molecular substance ... for the purpose of stimulating the growth of desired living tissue within the established space" (*see the abstract*)). Without the guidance provided by the instant specification – which cannot be considered when considering obviousness – there is no

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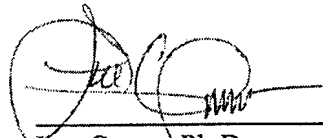
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motivation to swap one material for another between the two very different and apparently perfectly functional implants described in the prior art. On that basis alone, the present ground for rejection should be withdrawn.

Filed herewith is a Petition for Extension of Time. Please apply any charges or credits to deposit account 06-1050, referencing Attorney Docket No. 14188-002001.

Respectfully submitted,

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